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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,126	09/18/2006	Guido Grandi	002441.00187	4123

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NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

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07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,126	Applicant(s) GRANDI ET AL.	
	Examiner PADMA .V. BASKAR	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 January 2006.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Election/Restriction

1. Claims 1-27 are pending in the application.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-14 and 23 drawn to an immunogenic composition comprising a combination of GAS antigens, said combination two to ten or two to thirty-one GAS antigens, a kit comprising said immunogenic composition and a method.

Further restriction to one combination required (see Para # 4).

Group II, claims 15-17 drawn to fusion construct comprising a combination of GAS antigens.

Further restriction to one combination required (see Para # 4).

Group III, claims 18-20 and 27, drawn to a composition comprising a combination of two or more antibodies and an antibody specific to said composition and a kit comprising said immunogenic composition.

Further restriction to one combination required (see Para # 4).

Group IV, Claim 21 drawn to a method for the therapeutic or prophylactic treatment of Streptococcus pyogenes infection in an animal susceptible to streptococcal infection comprising administering to said animal a therapeutic or prophylactic amount immunogenic composition comprising GAS antigen.

Further restriction to one combination required (see Para # 4).

Group V, claim 22 drawn to a method for the therapeutic or prophylactic treatment of Streptococcus pyogenes infection in an animal susceptible to streptococcal infection comprising administering to said animal a therapeutic or prophylactic amount immunogenic composition comprising GAS antibodies.

Further restriction to one combination required (see Para # 4).

Group VI claims 24-26 drawn to a composition comprising a GAS 40 antigen, wherein said antigen comprises an amino acid sequence comprising a first coiled-coil region or a second coiled-coil region, wherein said GAS 40 antigen comprises a first coiled-coil region comprising

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SEQ ID NO: 12. wherein said GAS 40 antigen comprises a second coiled-coil region comprising SEQ ID NO: 13.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to antigens and antibodies and methods of using antigens and antibodies.

However, Telford et al WO 02/34771 disclose immunogenic composition comprising combination of GAS antigens (see page 2, line 1 - page 10, line 16 and claims)
Therefore, the technical feature of linking groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group I is considered to be immunogenic composition comprising two to ten or two to thirty-one GAS antigens.

The technical feature of Group II is considered to be fusion construct.

The technical feature of Group III is considered to be antibody or composition

The technical feature linking Groups IV-V is considered to be methods utilizing products that share no common structure, property and function so as to form a single general inventive concept under Rule 13.1.

The special technical feature of Group VI is considered to be a different composition comprising GAS 40 antigen and SEQ.ID.NO: 12 and 13.

DISTINCT INVENTIONS

4. For each group of inventions I-V above, restriction to any one combination comprising two to thirty one GAS antigens is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-V and any one combination of immunogenic composition that comprises two to thirty one GAS antigens

The claimed compositions share no common special technical feature because they have no common structure. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among immunogenic combination of compositions.

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Applicant is required under Restriction is required under 35 U.S.C. 121 and 372 to elect a single disclosed SEQ.ID.NO from any group elected.

5. Applicant is required, in reply to this action, to elect a group and one sequence and identify the SEQ.ID.NO to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Conclusion

6. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898.

Respectfully,

/Padma v Baskar/

Examiner, Art Unit 1645